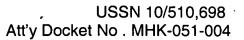
OTP E OCT 19 2005

384 Rec'd PCT/PTO 19 ₱€7-2005

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031

Under the Par	A PART PA	duction Action 4995	no nerson	s are red	U.S united to respond to a	 Patent and T collection of int 	Frademark formation :	Office; L	I.S. DEPARTMENT OF COMMERCE displays a valid OMB control number.
Onder We i a		RADEMA	no person.	Appli	cation Number	10/510,69		amoss it	
TRANSMITTAL FORM			Filing	Date	April 9, 20	003			
			First	Named Inventor	Berlin				
				Art U	Init	unassigne	ed		
/to be used for	all sames	andansa aftar initial	Flina)	Exan	niner Name	unassigne	ed .		
	- 	ondence after initial	nung)	Attor	ney Docket Number	MHK.051.	004		
Total Number of	Pages in	This Submission							
		٠	ENCI	LOSU	IRES (Check a	all that apply	y)		
☐ F6	Fee Transmittal Form Fee Attached Amendment/Reply After Final Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Disclosure Statement			Drawing(s) Licensing-related Papers Petition				Appeal Communication to Board of Appeals and Interferences Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)	
Af Af Extension				Provision Provis	to Convert to a conal Application of Attorney, Revoca e of Correspondence al Disclaimer of For Refund comber of CD(s)	e Address	ddress Copy Resp Print Disk		Proprietary Information Status Letter Other Enclosure(s) (please Identify below): by of Notification mailed 9/20/2005 ponse To Notification mailed 9/20/2005 btout of Sequence Listing kette containing Sequence Listing
Certified Copy of Priority Document(s)			Remar	ks					
Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53									
		SIGNA	TURE C	F AP	PLICANT, ATT	ORNEY, (OR AGI	ENT	
Firm Name	McIntyre	e Harbin & King			· · · · · · · · · · · · · · · · · · ·	<u> </u>	_		
Signature		Z			,				
Printed name	Lawrence	ce Harbin	`						
Date October 19, 2005			· ·	Reg. No. 27,644					
CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:									
Signature	2.0	571-273-8300 (P	TO centra	al fax)					
T		Lawrence Harbin						Date	October 19, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



IN THE LIGHTED STATES PATENT AND TRADEMARK OFFICE

In re of the Application of

Kurt Berlin

Group Art Unit: to be assigned
 US Serial Number: 10/510,698
 Examiner: to be assigned

35 U.S.C. 371 Filing Date: October 8, 2004

International Application Number: PCT/IB03/01791

•

International Filing Date: April 9, 2003 • Docket No.: MHK-051-004

For: METHOD FOR ANALYSIS OF
METHYLATED NUCLEIC ACIDS

•

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

RESPONSE TO NOTIFICATION OF DEFECTIVE RESPONSE DATED 09/20/2005 AND STATEMENTS UNDER37 CFR 1.822, AND/OR 1.823, AND 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d)

Dear Sir:

This letter responds to the Notification of Defective Response dated 09/20/2005 and accompanying Raw Sequence Listing Error Report (copies attached here), indicating that the paper or compact disc copy of the Sequence Listing is not the same as the computer readable form required by 37 CFR 1.821.1(e). Please be advised that we received only a partial Raw Sequence Listing (namely, only the first page of six pages total was forwarded to the undersigned) with the Error Report. The page containing the actual error in the sequence listing

USSN 10/510,698 DOCKET NO. MHK-051-004

was not forwarded with the September 20 Notification. Although we requested the additional

pages from Mr. Lamont Hunter of the PCT branch, our request was not satisfied. Mark Spencer

of the STIC branch was kind enough to troubleshoot the error over the telephone when provided

the serial number of the subject application.

Accordingly and in response, we are submitting:

1) a substitute (corrected) paper and CRF of the Sequence Listing in compliance with the

requirements of 37 CFR 1.822 and/or 1.823; and

2) an Amendment specifically directing its entry into the application, as requested. This is

the same Amendment previously filed on May 18, 2005, with the first CRF Sequence Listing.

The content of the sequence listing information recorded in computer readable form is

identical to the paper sequence listing. Additionally, as required by 37 CFR 1.821(e), 1.821(f),

1.821(g), 1.825(b) or 1.825(d), no new matter has been introduced in responding to the notice of

defective response.

Respectfully,

Lawrence Harbin

Reg. No. 27,644

Date: October 19, 2005

2



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

U.S. APPLICATION NUMBER NO. FIRST NAMED APPLICANT ATTY. DOCKET NO. 10/510,698 Kurt Berlin MHK-051-004

INTERNATIONAL APPLICATION NO.

25582 LAWRENCE HARBIN MCINTYRE HARBIN & KING LLP 500 9TH STREET, S.E. WASHINGTON, DC 20003

PCT/IB03/01791 I.A. FILING DATE PRIORITY DATE 04/09/2003 04/09/2002

CONFIRMATION NO. 4311 371 FORMALITIES LETTER *OC000000017051542*

Date Mailed: 09/20/2005

NOTIFICATION OF DEFECTIVE RESPONSE

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495)

- Indication of Small Entity Status
- Priority Document
- Copy of the International Application filed on 10/08/2004
- Copy of the International Search Report filed on 10/08/2004
- Biochemical Sequence Diskette filed on 05/18/2005
- Oath or Declaration filed on 10/08/2004
- Biochemical Sequence Listing filed on 05/18/2005
- Small Entity Statement filed on 10/08/2004
- Request for Immediate Examination filed on 10/08/2004
- U.S. Basic National Fees filed on 10/08/2004
- Power of Attorney filed on 10/08/2004

Applicant's response filed 05/18/2005 is hereby acknowledged. The following requirements set forth in the NOTIFICATION of MISSING REQUIREMENTS mailed 03/18/2005 have not been completed.

- The paper or compact disc copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e). Applicant must provide a substitute paper or compact disc copy of the "Sequence Listing", as well as an amendment specifically directing its entry into the application OR a substitute computer readable form (CRF) copy of the "Sequence Listing". These two items must be the same. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).
- · A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content

of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

Applicant is required to complete the response within a time limit of ONE MONTH from the date of this Notification or within the time remaining in the response set forth in the Notification of Missing Requirements, whichever is the longer. No extension of this time limit may be granted under 37 CFR 1.136, but the period for response set in the Notification of Missing Requirements may be extended under 37 CFR 1.136(a).

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice **MUST** be returned with the response.

LAMONT M HUNTER

Telephone: (703) 308-9140 EXT 201

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/510,698	PCT/IB03/01791	MHK-051-004

FORM PCT/DO/EO/916 (371 Formalities Notice)

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number:	10/5/0),6	98_	
Source:		,	POTI	10
Date Processed by STIC:	-2/	5/	05	

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,

2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.2.2 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail. Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

- 1. EFS-Bio (<http://www.uspto.gov/ebc/efs/downloads/documents.htm>, EFS Submission User Manual ePAVE)
- 2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
- 3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05):
 U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street,
 Alexandria, VA 22314

Revised 01/24/05...

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75/18T

JIA M

Raw Sequence Listing Error Summary

	TO SOFTWARF
ATTN: NEW RULES CASES: P	PLEASE DISREGARD ENGLISH "ALPHA" HEADERS. WHICH WERE INSERTED BY PTO SOFTWARE
Wrapped Aminos v	The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
	The rules require that a line not exceed 72 characters in length. This includes white spaces.
	The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
4Non-ASCII	The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
	Sequence(s) contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
"bug"	A "bug" in Patentin version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) Normally, Patentin would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
(OLD RULES)	Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence: (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) (i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading) (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) This sequence is intentionally skipped
•	Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to Include the skipped sequences.
(NEW RULES)	Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence. <210> sequence id number <400> sequence id number 000
9Use of n's or Xaa's (NEW RULES)	Use of n's and/or Xaa's have been detected in the Sequence Listing. Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present. In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
10Invalid <213> Response	Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence
Use of <220>	Sequence(s) missing the <220> "Feature" and associated numeric identifiers and responses. Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section. (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
12Patentin 2.0	Please do not use "Copy to Disk" function of Patentin version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
13Misuse of n/Xaa	"n" can only represent a single nucleotide; "Xaa" can only represent a single amino acid
4.78.000.70	AMCar Biotechnology Systems Branch - 09/09/2003



 \mathtt{PCT}

RAW SEQUENCE LISTING DATE: 07/05/2005
PATENT APPLICATION: US/10/510,698 TIME: 11:16:36

Input Set : A:\MHKBERLIN.ST25.txt

Output Set: N:\CRF4\07052005\J510698.raw

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3 <110> APPLICANT: EPIGENOMICS AG
        BERLIN, KURT
 6 <120> TITLE OF INVENTION: METHOD FOR ANALYSIS OF METHYLATED NUCLEIC ACIDS
 8 <130> FILE REFERENCE: MHK-051-004
10 <140> CURRENT APPLICATION NUMBER: US 10/510,698
11 <141> CURRENT FILING DATE: 2004-10-08
13 <150> PRIOR APPLICATION NUMBER: PCT/IB03/01791
14 <151> PRIOR FILING DATE: 2003-04-09
16 <150> PRIOR APPLICATION NUMBER: US 60/370,690
17 <151> PRIOR FILING DATE: 2002-04-09
                                                            Doas Not Comply
                                                        orrected Diskette Neede
19 <160> NUMBER OF SEQ ID NOS: 15
21 <170> SOFTWARE: PatentIn version 3.0
23 <210> SEQ ID NO: 1
24 <211> LENGTH: 22
25 <212> TYPE: DNA
26 <213> ORGANISM: Artificial
28 <220> FEATURE:
29 <223> OTHER INFORMATION: oligonucleotide primer
31 <400> SEQUENCE: 1
32 ttttcgtcgt tttaggttat cg
                                                                          22
35 <210> SEQ ID NO: 2
36 <211> LENGTH: 23
37 <212> TYPE: DNA
38 <213> ORGANISM: Artificial
40 <220> FEATURE:
41 <223> OTHER INFORMATION: oligonucleotide primer
43 <400> SEQUENCE: 2
44 tttttgttgt tttaggttat tgg
                                                                          23
47 <210> SEQ ID NO: 3
48 <211> LENGTH: 26
49 <212> TYPE: DNA
50 <213> ORGANISM: Artificial
52 <220> FEATURE:
53 <223> OTHER INFORMATION: oligonucleotide probe
55 <400> SEQUENCE: 3
56 ttcggacgtc gttgttcggt cgatgt
                                                                          26
59 <210> SEQ ID NO: 4
60 <211> LENGTH: 23
61 <212> TYPE: DNA
62 <213> ORGANISM: Artificial
64 <220> FEATURE:
65 <223> OTHER INFORMATION: oligonucleotide primer
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67 <400> SEQUENCE: 4

RAW SEQUENCE LISTING DATE: 07/05/2005
PATENT APPLICATION: US/10/510,698 TIME: 11:16:36

Input Set : A:\MHKBERLIN.ST25.txt

Output Set: N:\CRF4\07052005\J510698.raw

68 tttttgttgt tttaggttat tgg	23.
71 <210> SEQ ID NO: 5	
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74 <213> ORGANISM: Artificial	
76 <220> FEATURE:	
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83 <210> SEQ ID NO: 6	
84 <211> LENGTH: 26	
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88 <220> FEATURE:	
89 <223> OTHER INFORMATION: oligonucleotide probe	
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96 <211> LENGTH: 17	
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100 <220> FEATURE:	
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103 <400> SEQUENCE: 7	
104 cggatacgat ttcgggg	17
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109 <212> TYPE: DNA	
110 <213> ORGANISM: Artificial	•
112 <220> FEATURE:	
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115 <400> SEQUENCE: 8	
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122 <213> ORGANISM: Artificial	
124 <220> FEATURE:	
125 <223> OTHER INFORMATION: oligonucleotide probe	
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131 <210> SEQ ID NO: 10	
132 <211> LENGTH: 19	
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136 <220> FEATURE:	
137 <223> OTHER INFORMATION: oligonucleotide primer	
139 <400> SEQUENCE: 10	
140 tggatatgat tttggggta	19

RAW SEQUENCE LISTING

PATENT APPLICATION: US/10/510,698

DATE: 07/05/2005 TIME: 11:16:36

Input Set : A:\MHKBERLIN.ST25.txt

Output Set: N:\CRF4\07052005\J510698.raw

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158 <213> ORGANISM: Artificial

160 <220> FEATURE:

161 <223> OTHER INFORMATION: oligonucleotide probe

163 <400> SEQUENCE: 12

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167 <210> SEQ ID NO: 13 168 <211> LENGTH: 25

169 <212> TYPE: DNA

170 <213> ORGANISM: Artificial

172 <220> FEATURE:

173 <223> OTHER INFORMATION: oligonucleotide primer

175 <400> SEQUENCE: 13

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181 <212> TYPE: DNA

182 <213> ORGANISM: Artificial

184 <220> FEATURE:

185 <223> OTHER INFORMATION: oligonucleotide primer

187 <400> SEQUENCE: 14

188 tgggattgag ggtaagaggg at

191 <210> SEQ ID NO: 15

192 <211> LENGTH: 22

193 <212> TYPE: DNA

194 <213> ORGANISM: Artificial

196 <220> FEATURE:

197 <223> OTHER INFORMATION: /artificial sequence

199 <400> SEQUENCE: 15

200 attagtttcg tttaaggttc ga

insufficient explanation - what is source?

(see item!)

22 on Even

Summany

Sheet)

RAW SEQUENCE LISTING ERROR SUMMARY DATE: 07/05/2005
PATENT APPLICATION: US/10/510,698 TIME: 11:16:37

Input Set : A:\MHKBERLIN.ST25.txt

Output Set: N:\CRF4\07052005\J510698.raw

Invalid <213> Response:

Use of "Artificial" only as "<213> Organism" response is incomplete, per 1.823(b) of New Sequence Rules. Valid response is Artificial Sequence.

Seq#:1,2,3,4,5,6,7,8,9,10,11,12,13,14,15

VERIFICATION SUMMARY

DATE: 07/05/2005

PATENT APPLICATION: US/10/510,698

TIME: 11:16:37

Input Set : A:\MHKBERLIN.ST25.txt

Output Set: N:\CRF4\07052005\J510698.raw